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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,980

12/09/2003

George Chin-Sheng Chou

18106-112

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12/12/2008

WPAT, PC

INTELLECTUAL PROPERTY ATTORNEYS

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

12/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

1. Applicants' Response to Office Action, received 5 September 2008, is acknowledged.

Claims 1, 3, 4, 5, 6, 7, 11, 12, 13 and 14 have been amended. New claims 21-27 have been added.

2. Claims 1-7, 11-14 and 21-27 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claims 1-7 and 11-14 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shimada et al (*Rinsho Byori*, Vol. 50, No. 5, pages 528-532, May 2002) is withdrawn in light of the claim amendments and applicants' arguments.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7 and 23-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 1 now recites a method of detecting a microorganism where in step (d) the second PCR DNA is hybridized with a probe attached to magnetic beads, "in which the probe comprises a nucleotide sequence specific for hybridizing with the second PCR DNA product". Thus use of the open language "comprises" permits any number of other nucleotides

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on either end of the specific sequence. Thus, these unknown regions may not be specific for the second PCR DNA products, but may nonspecifically hybridize. It is unclear how one distinguishes such nonspecific hybridization from the specific hybridization due to the only known sequence.

Claims 2-7 and 23-27 are dependent claims, but do not clarify the issue.

6. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 3 now recites that both the outer and inner pair of primers "comprise" specific sequences. The use of the open language "comprise" permits any number of other nucleotides on either end of the specific sequences. Thus, it is unclear how one distinguishes PCR products due only to the specified sequences and those which may be due solely to the unknown regions of the primers.

7. Claims 11-14, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 11 now recites that both the forward and reverse pair of primers "comprise" specific sequences. Newly added claim 21 recites that the outer pair and inner pair of primers "comprise" specific nucleotide sequences. The use of the open language "comprise" permits any number of other nucleotides on either end of the specific sequences. Thus, it is unclear how one distinguishes PCR products due only to the specified sequences and those which may be due solely to the unknown regions of the primers.

Claims 12-14 and 22 are dependent claims, but do not clarify the issue.

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Conclusion

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

November 24, 2008